



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/530,795 06/25/00 KELLER

B 270142000300

SM

THOMAS G WISEMAN
MORRISON & FOERSTER
2000 PENNSYLVANIA AVENUE NW
WASHINGTON DC 20006-1888

IM22/0926

EXAMINER

HENDRICKS, K

ART UNIT	PAPER NUMBER
----------	--------------

1761

DATE MAILED:

09/26/01

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/530,795

Applicant(s)

Keller

Examiner

Group Art Unit

1761

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-14 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-14 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☒ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1761

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

NOTE: This application is an English translation of a foreign document. *Applicants' representative is strongly encouraged to review the application, especially the claims, to comply with accepted U.S. Patent structure and language.* The claims are generally narrative and indefinite, failing to conform with current U.S. practice, and are replete with grammatical and idiomatic errors. *The rejections under 35 USC 112 2nd paragraph below are an attempt to call attention to these occurrences, yet may not be comprehensive.*

- Claim 1, and thus its dependent claims, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The recitation of claim 1 is disjointed in its elements; it is unclear as to the physical and functional relationship between the liposomes, and any nutrients and "ingredients". The liposomes are simply present "in amounts to enhance" certain activities of (non-specific) ingredients, yet these ingredients are not specifically recited as present within the composition. See also claim 9.
- The terms "enhance" and "stabilize" are relative terms which render the claims indefinite. The terms are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree and starting point over which the formulations are

Art Unit: 1761

"stabilized" or "enhanced", and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

- It is unclear as to what is intended by "nutritional delivery of nutrients", as opposed to simply the "delivery of nutrients". Further, it is unclear into what body the "delivery" is intended.
- In claim 2, the phrase "selected from or mixtures thereof" is an improper Markush-type listing of components. A closed group should contain components which are "selected from A, B, C and D".
- In claim 3, the phrase "in the range of" is indefinite. It is unclear if this language indicates an actual, specific range, or if this is a means to list non-specific amounts of lipids, similar to "around". It is suggested that the phrase be amended to "within the range of".
- It is unclear as to what constitutes a "typical" size range in claim 4. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.
- Regarding claim 7, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
- Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Given the current recitation of the claim, it is unclear if carrageenan is to be present within the formulation, or if it is to be excluded from the components. Note that claims 6 and 1, from which claim 8 depends, are open claims which "comprise" carrageenan, and there is no positive limitation to state that this should not be present.

Art Unit: 1761

- Claim 8 is further complicated by the attempt to incorporate active language ("wherein bilayer forming lipids assemble into liposomes which act...") into a composition claim.
- The phrase "bilayer forming lipids" should be "bilayer-forming lipids".
- Claim 9 is indefinite, as given the language of claim 1 from which it depends, nutrients and other "ingredients" must necessarily be present, in order for the formulation to be functional ("in amounts to enhance nutritional delivery of nutrients", etc. in claim 1).
- The use of the trademark "Phospholipon 90H..." has been noted in this application, and in claim 11. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.
Further, the (trademark) phrase in parentheses renders the claim indefinite because it is unclear whether the limitations within the parentheses are part of the claimed invention, if it is merely exemplary, or if this is simply further defining as the only "purified phospholipid from soy", and that there is no known other available to confuse the issue.
See MPEP § 2173.05(d).
- Claim 11 is indefinite as to the wording and grammar of the claim, leaving unclear the metes and bounds of the intended invention. It is even unclear if the soy lipids are part of the liposome, as the formulation merely "has" these lipids present.
- In claim 13, part (a), it is unclear if all the ingredients listed therein are to be encapsulated simultaneously, as the claim states that the process should comprise "encapsulating nutrients, vitamins, immunoglobulins, proteins...". The phrase that follows, "or mixtures thereof" does not serve to clarify this issue.

Art Unit: 1761

- The phrase "and other ingredients", at part (c) of claim 13, is indefinite, as it is unclear as to what types, forms, amounts and functions of ingredients are encompassed by this phrase.

Numerous grammatical errors appear in the claims. They include the following:

- In claim 2, line 1, the term "said" is suggested to be placed between "wherein" and "liposomes".
- In claim 5, line 1, "liposome" should be "liposomes" (plural).
- Similarly, in claim 6, "emulsions" should be "emulsion" (singular).
- In claims 6-7 and 9-11, the term "which" is suggested to be added after the phrase "claim 1".
- Claim 10 requires a period (.) at the end.
- In claim 13, last line, the term "powder" should be "powdered".
- In claim 14, the first word, "A", should be "The".
- In claim 14, line 1, the term "the" should be inserted between "preparing" and "infant".
- In claim 14, last line, it is suggested that the phrase "reform forming" be amended to state "reform to form", or "reform to produce".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehansho et al.

Mehansho et al. discloses the production of "bilayer-forming emulsifiers in nutritional compositions" containing "highly bioavailable iron sources". The prior art section discloses the previous disadvantages experienced when such "highly bioavailable" iron compounds as ferrous sulfate (bottom, col. 1), ferrous fumarate or ferrous succinate (mid-col. 8) are utilized in various chocolate milk beverages and powders. The compositions are formed when an edible substrate is coated "with an effective amount of an emulsifier capable of forming a bilayer structure" (col. 3),

Art Unit: 1761

and may also include a bilayer stabilizer. Other nutritional ingredients may be included in the composition, such as: milk proteins including dried whey (col. 10), fats, oils, vitamins, minerals, and thiamine HCL (col. 7-8). Food-grade emulsifiers are employed (col. 6, 11), and the composition may be dried, and/or incorporated into various foodstuffs such as baby foods and formulas (mid-col. 4). The emulsifiers include various phospholipids and glycolipids. Commonly-known stabilizers may be incorporated into the composition, such as cholesterol or stigmastanol (bottom col. 6), and various edible substrates include hydrogenated soybean oil (mid-col. 6). The percentage amounts and relative ranges of these compounds are provided at columns 7-8 and in the examples.

Thus, the claimed invention is anticipated by the reference. The concept of encapsulating various vitamins and nutrients within bilayered liposomes was known, as was their subsequent drying, and use within various foodstuffs such as infant formulas. Regarding certain particular dependent claim limitations, the stated amounts of the components of the referenced composition fall within the instant ranges claimed. Regarding the concentrations of phospholipids (claim 10) and the size of the liposomes (claim 4), these are considered to be inherent properties of the specifically disclosed compositions of the reference, absent any clear and convincing evidence and/or arguments to the contrary. Immunoglobulins (instant claim 9) are naturally found in milk and various solid, dried or liquid milk preparations, as well as being present in most infant formulas.

Finally, regarding the combined use of thiamine HCL and ferrous sulfate (claim 12), it is noted that the reference includes both as potential ingredient components: thiamine HCL at the middle of column 8, and ferrous sulfate is both encompassed by the general teaching of nutritional, "highly bioavailable" ferrous sources, and specifically at the teachings of the prior art at columns 1-3. It is important to note that the characteristics of oxidation of vitamins and formation of undesirable gray color of the formula, which were attributed to iron compounds such as ferrous sulfate (col. 1-2), were also specifically noted as characteristics of other ferrous salts

Art Unit: 1761

such as ferrous fumarate and ferrous succinate (mid-col. 2, mid-col. 8), the two compounds exemplified by the reference. The invention taught by the reference is the means to overcome these undesirable characteristics, such that the iron compounds are isolated away from other nutrients, by the presence of the liposomes. Thus, the reference discloses the prior use of ferrous sulfate and ferrous fumarate within such formulations, and provides a positive solution for the incorporation of these iron (ferrous) sources.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano, can be reached at (703) 308-3959. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3602.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


KEITH HENDRICKS
PRIMARY EXAMINER